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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/945,249	02/02/1998	RICHARD ANTHONY VERE HODGE	P31158	2467
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THOMAS HOXIE NOVARTIS, CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 430/2 EAST HANOVER, NJ 07936-1080			EXAMINER	
			TRAVERS, RUSSELL S	
		ART UNIT	PAPER NUMBER	
		1617		

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

*faxed to  
Thomas Savitsky  
973-781-6064  
on 7/16/03*

## Office Action Summary

Application No. <b>08/945,249</b>	Applicant(s) <b>Vere Hodge et al</b>
Examiner <b>R.S. Travers J.D., Ph.D.</b>	Art Unit <b>1617</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Oct 10, 2000

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1,14 and 16-20 is/are pending in the application.

4a) Of the above, claim(s) 1, 3, and 5-14 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1, 4, and 16-20 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

Art Unit:

The request for reconsideration filed October 10, 2000 has been received and entered into the file.

Applicant's arguments filed October 10, 2000 have been fully considered but they are not deemed to be persuasive.

Claims 1, 3-14 and 16-20 are presented for examination.

Applicant's election with traverse of Group I, claims 1 and 4 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that restriction was not required in the international examination process. This is not found persuasive because failure to require additional fees to examine all included inventions fails to preclude the instant restriction..

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 5-14 drawn to an invention non-elected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 4 and 16-20 will be examined to the extent they read on the elected subject matter.

Claims 3 and 5-14 reading on non-elected subject matter are withdrawn from consideration.

Art Unit:

Applicant's arguments filed January 21, 2000 have been fully considered but they are not deemed to be persuasive.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 4 and 16-20 are rejected under 35 U.S.C. § 103 as being unpatentable over Kenig et al or Boyd et al, all of record..

Kenig et al or Boyd et al, all of record. teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicament are taught as useful for treating those viral diseases herein claimed. Claims 1, 4 and 16-20, and the primary references, as to:

1) various isomers employed as the preferred therapeutic agents.

The skilled artisan, possessing a compound for a particular therapeutic use possesses all isomers, analogs, homologs, bioisosteres, acids, esters and salts of such

Art Unit:

compounds for that same use. In the instant case, the claims read on employing compounds residing in the prior art, for the same use. Absent information illustrating some unexpected benefit residing in those prior art compounds, unidentified in the prior art; the instant claims, reading on obvious subject matter remain properly rejected as obvious.

### **RESPONSE TO ARGUMENTS**

As stated above, the skilled artisan, possessing a compound for a particular therapeutic use possesses all isomers, analogs, homologs, bioisosteres, acids, esters and salts of such compounds for that same use. In the instant case, the claims read on employing compounds residing in the prior art, for the same use. Absent information illustrating some unexpected benefit residing in those prior art compounds, unidentified in the prior art; the instant claims, reading on obvious subject matter remain properly rejected as obvious.

Additionally, the Examiner cited prior art teach a ciral center in the claimed compound, and the skilled artisan possesses that information required for separation of such optical isomers. It is well settled patent law that the skilled artisan, knowing a compound contains an asymmetric carbon atom, possesses all resultant optical isomers. The skilled artisan in possession of a compound for a specific therapeutic use, possesses all isomeric forms of the compound for the old and well known antiviral utility. It is well known in the pharmaceutical art that various optical isomers will exhibit

Art Unit:

biological effects at various levels. Absent unexpected benefits residing in these old and well known compositions and methods for their use, the instant claims are properly rejected under 35 USC 103.

Applicants are claiming methods for using penciclovir compositions to treat viral diseases. As stated above, the Examiner cited prior art teaches penciclovir as a racemic mixture, placing the skilled artisan in possession of all isomers. Absent some difference in kind between the various isomers the skilled artisan would have seen each isomer as *prima facie* obvious (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)). The skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels. Possessing a compound known to contain ciral centers, places all the resultant compounds in the skilled artisan's possession. It would follow therefore, the instant claims recite *prima facie* obvious subject matter and are properly rejected under 35 USC 103, and 35 USC 102. It is noted that all references cited by Examiner teach the claimed penciclovir as effective against viral diseases, as claimed herein. Thus, use of one or another optical isomer by the skilled artisan would have seen as *prima facie* obvious, absent some difference in kind between the various isomers (see *In re Adamson and Duffin*, 125 USPQ 233 (CCPA 1960)).

It is well settled patent law that optical isomers would have been expected to possess different therapeutic activities. Most biological systems are sensitive to

Art Unit:

optical isomerism, motivating the skilled artisan to expect one or another optical isomer to effect greater, or lesser physiological activity.

Applicants aver a showing of unexpected benefits residing in the specification at page 4; Examiner was unable to locate a showing of unexpected benefits. As stated below; evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither clear, nor convincing or reasonably commensurate in scope with the instant claims. Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103. Evidence supporting un-obviousness by virtue of possessing unexpected benefits must be submitted in declaration form. All information in the specification is attested, as should any information subsequently filed. If Applicants attest to published data, that such data was done at their direction and guidance; these averments will support averments of un-obviousness.

Examiner cited prior art teaches those phosphate esters herein envisioned. The Examiner cited prior art taught the instant compounds as possessing chiral atom, thus, producing optical isomers. Possessing a compound for a medicinal use, this skilled artisan possesses all isomers for this compound. Absent a illustration of unexpected

Art Unit:

benefits residing in one, or another, isomer these uses are obvious to the skilled artisan.

The references herein relied upon establish a strong prima facie case of obviousness as to applicants' invention. The claimed subject matter is of such a nature that the differences between said subject matter and the teachings of the prior art of record would have rendered applicants' subject matter as a whole obvious to those skilled in the art at the time of applicants' invention. The references clearly establish that the claim designated components were old, of known character and that one skilled in the art would have been motivated to employ said components in the manner herein claimed to obtain the claimed, expected results. The claims are therefore properly rejected under 35 USC 103.

Applicant avers the presence of unexpected benefits in the claimed subject matter, yet fails to illustrate such. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is neither clear, nor convincing or reasonably commensurate in scope with the instant claims. Absent claims commensurate with the showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

Art Unit:

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



**Russell Travers J.D., Ph.D.  
Primary Examiner  
Art Unit 1617**